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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,823	10/05/2001	Gilles Gutierrez	GEI-088	4121

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EXAMINER

BERMAN, ALYSIA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,823

Applicant(s)

GUTIERREZ ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Receipt is acknowledged of the information disclosure statement filed September 4, 2001, the declaration, assignment and preliminary amendment filed October 5, 2001 and the response to notification of missing parts filed October 23, 2001. Claim 1 has been canceled. Claims 2-11 have been amended. Claim 12 has been added. Claims 2-12 are pending.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

3. Applicant is reminded of the proper content of an abstract of the disclosure.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

4. The abstract of the disclosure is objected to because of the word novel in line 1. Deletion of this word is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an extract of *Padina pavonica*, does not reasonably provide enablement for an extract of algae from the *Dictyotale* family. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification states at page 3, 2nd paragraph that extracts of a *Dictyotale*, namely *Padina pavonica*, have no effect on proliferation of cells while amplifying the maturation of keratinocytes by a better expression of desmosomial proteins and cytokeratins. The specification does not disclose that any other species of alga from this family provides these benefits. Extracts of different plants even from the same family would not necessarily be expected to exhibit the same properties or provide the same benefits because of the chemical makeup of the extracts may be different. It would take undue experimentation for one skilled in the art to determine what species of algae from the *Dictyotale* family other than *Padina pavonica* would provide the effects instantly claimed. Therefore, the specification is only enabled for those species of algae disclosed.

7. Claims 2-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the maturation of keratinocytes, amplifying the synthesis of cytokines and increasing desmosomial proteins in warm-blooded animals, does not reasonably provide enablement for limiting the problems connected to ageing. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not provided any disclosure or guidance as to what problems associated with ageing are limited or how they are limited. The specification discloses that the extract of *Padina pavonica* has no effect on cellular metabolism and cellular proliferation in the skin. Having no effect is not the same as limiting cellular metabolism and cellular proliferation in the skin. Further, one skilled in the art could not extrapolate that having no effect on cellular metabolism and cellular proliferation in skin would reasonably lead to the conclusion that topical application of the extract would limit other problems associated with ageing such as Alzheimer's disease. Further, Applicant has not provided any standard by which to measure that the problems connected with ageing have been limited. It would take undue experimentation for one skilled in the art to determine what problems connected with aging are affected by topical application of the extract and how they are limited.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

9. Claims 2-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The claims are indefinite because it is unclear what Applicant intends to encompass by problems connected to ageing. The specification does not provide any guidance as to what the problems connected with ageing are.

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11. The claims are indefinite because it is unclear how the problems of ageing are limited. The problems connected with ageing are not defined and how they are limited has not been disclosed.
12. The claims are vague and indefinite because it is unclear if the name of the plant Applicant is claiming is the scientific name or the common name. The proper way to write a scientific name is to capitalize the family and genus and italicize the entire name.
13. Claim 2 recites the limitation "the active extract" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
14. Claim 2 is vague and indefinite because it is so confusing that what Applicant intends to claim cannot be determined.
15. Claims 2-6 are indefinite because it appears that they are directed to either a method of obtaining an extract or a method of making a composition. However, the independent claim that these claims depend from is directed to a method of using a composition. It is unclear what Applicant intends to claim.
16. Claims 3, 7 and 8 recite the limitation "the active principle." There is insufficient antecedent basis for this limitation in the claim.
17. Claim 5 is vague and indefinite because "Padona" appears to be misspelled. All of the other claims recite, "Padina."
18. Claim 10 recites the limitation "active principle" in line 3. There is insufficient antecedent basis for this limitation in the claim.
19. Claim 5 is vague and indefinite because it is unclear if Applicant intends that the extract is incorporated into a support or vehicle either in an oily phase or dry or if it can

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be provided either incorporated into a support or vehicle in an oily phase or provided dry.

20. Claim 6 is vague and indefinite because it recites, "a silicone oil is added to the solution by produce a fluid emulsion." This does not make grammatical sense and, so, is unclear.

21. Claim 10 is vague and indefinite because it is unclear what a Unite of activity is.

22. This application is replete with 35 U.S.C. 112 issues. The above are just some examples. Applicant is required to review all of the claims for 35 U.S.C. 112 issues and make appropriate corrections.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 2-6, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by "Synthesis from the sea," Soap, Perfumery and Cosmetics, Vol. 72(5):63 (05/1999).

"Synthesis from the sea" discloses that the use of cosmetic formulations containing an extract of *Padina pavonica* helps protect the skin against free radicals and other irritations. It is known in the art that free radicals are associated with ageing. This disclosure implies the topical application of compositions containing a *Padina pavonica* extract.

Any properties exhibited by the composition or effects provided by the application of the composition are inherent and are not given patentable weight. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP §2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product.

The claims are directed to a process of using a composition not a process of making a composition. Therefore, the limitations of claims 2-6 regarding how the extract and the composition are obtained are not given patentable weight over the prior art.

25. Claims 3-6, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,961,981 (981).

US '981 discloses topical application of cosmetic compositions containing an extract obtained from a algae of the family Dictyotales (title, abstract, col. 1, lines 21-34, col. 5, lines 40-44, col. 6, lines 64-66 and the example at col. 13, lines 33-46). The extract can be obtained by maceration or lixiviation in ethanol followed by purification and elution using an HPLC with a C18-grafted silica and a methanol/water eluent (col. 4, lines 1-19). For extraction with ethanol or acetone followed by evaporation until dry see column 2, lines 18-49. For dispersion or incorporation of the extract onto a support or vehicle see column 5, lines 11-13 and the examples at column 11 and column 13. For polyethylene glycol see column 2, lines 45-46. For fluid emulsions see column 12, line 64 to column 13, line 4.

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

28. Claims 2-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Synthesis from the sea," Soap, Perfumery and Cosmetics, Vol. 72(5):63 (05/1999).

"Synthesis from the sea" discloses all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not explicitly disclose applying the composition onto the body of a warm-blooded animal nor does it disclose the concentration of the extract in grams per kilogram or units (UA).

"Synthesis from the sea" discloses cosmetic composition containing an extract of *Padina pavonica* that protects the skin. It is well known in the art to apply cosmetic compositions to the body of a person. It is within the skill in the art to select optimal

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parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). It would have been obvious for one skilled in the art to vary the proportions of components in a composition to arrive at the best compositions for the intended purpose. "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); see also *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc). Therefore, absent evidence of unexpected results over the prior art, the concentration of the extract is not considered critical to the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of "Synthesis from the sea" using optimal concentrations of ingredients and apply the composition to the body of a warm-blooded animal such as a person with the reasonable expectation of protecting the skin from free radicals.

29. Claims 2-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,961,981 (981).

US '981 teaches all of the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach elution for a period between 9 and 12 minutes or the concentration of extract.

US '981 teaches from column 3 to column 4 that the period of elution can be adjusted. It is within the skill in the art to select optimal parameters in a composition in

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order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). It would have been obvious for one skilled in the art to vary the proportions of components in a composition to arrive at the best compositions for the intended purpose. "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); see also *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc).

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '981 using optimal parameters in order to achieve optimal skin protection effects.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysja Berman
Patent Examiner
May 29, 2002


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